



Application Serial No. 09/850,061

Attorney Docket No. 033315-002

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REMARKS

I. CLAIM STATUS & AMENDMENTS

As correctly indicated on the Office Action Summary, claims 1-37 were previously pending in this application. However, Applicants, by way of the present Amendment, hereby cancel claims 1-11 and 19-34 without prejudice to or disclaimer thereof. Applicants reserve the right to file a continuation on any subject matter canceled by way of this Amendment.

The present Amendment also amends claims 12-18 and 35-37. Support for the amendments to claims 12-18 can be found, at least, in original claims 12-18, respectively, and in claim 11. Support for the amendments to claims 35-37 can be found, at least, in original claims 11-24, respectively. Thus, no prohibited new matter is believed to have been added by these amendments.

The present Amendment further adds new claims 38-41. Support for new claims 38, 40, and 41 can be found, at least, in canceled claims 11, 27 and 28, respectively. Support for new claim 39 can be found in the Specification, at least, on page 8, lines 12-24 and page 14, lines 32-33. Thus, no prohibited new matter is believed to have been added by these amendments.

Upon entry of the present Amendment, claims 12-18 and 35-41 will be pending.

II. RESPONSE TO RESTRICTION REQUIREMENT

A. Restriction

In response to the outstanding Restriction Requirement, Applicants elect with traverse Group II drawn to a method of using the peptides of formula (I) to inhibit polymerization of amyloid β peptide. Applicants submit that elected Group II corresponds, at least, to amended claims 12-18 and 38-41. For example, claims 12-18, 38, and 40-41 (*i.e.*, former claims 11-18, 27, 28, 32, and 34 of Group II) are drawn to methods of using peptides of formula (I) to inhibit polymerization of amyloid β peptide. Also, claim 39 (*i.e.*, former claim 33 of Group II) is drawn to methods of treating Alzheimer's disease. Applicants further submit that amended claims 35-37, which correspond to Groups VII-IX, respectively, should also be rejoined and examined together with the claims of elected Group II for, at least, the reasons noted herein below.

Applicants respectfully traverse the Restriction Requirement for at least the following reasons, and submit that claims 12-18 and 35-41 should be examined together.

First, with respect to groups II, III, VII, VIII, and IX, Applicants respectfully submit that Unity of Invention (*i.e.*, the specific compounds of Formula (I) that inhibit polymerization of the amyloid peptide) exists between these groups. In this regard, the specific compounds of Formula I, which are capable of inhibiting polymerization of the amyloid peptide, are the unitary invention. These specific compounds of Formula I are also the common core structure between the compounds encompassed by the claims.

Second, it is respectfully submitted that groups II, III, VII, VIII, and IX, all pertain to the same class and subclass and therefore, would not impose a serious burden on the Examiner to examine all these groups. In addition, the claims should be examined together

as they are all directed to compounds having the same inhibitory activity. Indeed, the search for such claims should be substantially, if not entirely, coextensive.

Under statute, an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct. See M.P.E.P. § 806.04 to § 806.04(j) (independent); see also M.P.E.P. § 806.05 to § 806.05(i)). Moreover, according to the M.P.E.P., there are two criteria for proper requirement for restriction between patentably distinct inventions:

- 1) The invention must be **independent** (M.P.E.P. § 802.01, § 806.04 and § 808.01) or **distinct** as claimed (M.P.E.P. § 806.05 to § 806.05(I)); **and**
- 2) There must be a **serious burden** on the Examiner if restriction is not required (M.P.E.P. § 803.02, § 806.04(a to j) and § 808.01(a) and § 808.02)).

These two criteria must **both** be met for the restriction requirement to be proper. Applicants believe that searching and examining the invention as now defined in claims 12-18 and 35-41, corresponding to groups II, III, VII, VIII and IX, **would not cause a serious burden** on the Examiner. No *prima facie* case regarding a serious burden on the Examiner has been shown by appropriate explanation of separate classification or separate status in the art or different field of search (the subject matter of the claims are all classified in class 514, subclass 02+), as defined in M.P.E.P. § 808.02. Thus, it is believed that no serious burden is imposed on the Examiner for searching these inventions. Therefore, one of the two requirements for a proper restriction is not met.

Therefore, Applicants respectfully request withdrawal of the Restriction

Requirement and examination on the merits of claims 12-18 and 35-41, as hereby amended.

B. Species Requirement

Applicants hereby elect with traverse the following constituents such that they read on SEQ ID NO. 8 (*i.e.*, the HHQKL VFF peptide) as follows:

As to R₁, Applicants elect with traverse Hydrogen.

As to A', Applicants elect with traverse Histidine-Histidine-Glutamine (designated "HHQ"). Applicants note that A' as a direct bond or an α -amino acid bonded at the carboxyl terminal of the α -carboxy group or a di-, tri-, tetra-, or pentapeptide bonded at the carboxyl terminal of the α -carbonyl group. See Specification, page 6, lines 31-34; claim 35. Thus, A' can be elected to read on the tripeptide of Histidine-Histidine-Glutamine (designated "HHQ").

As to Y', Applicants elect with traverse the amino acid Lysine (designated "K").

As to X', Applicants elect with traverse Valine (designated "V").

As to Z', Applicants elect with traverse Phenylalanine (designated "F").

As to B', Applicants elect with traverse Phenylalanine (designated "F").

As to R₂, Applicants elect with traverse Hydrogen.

Thus, as can be seen above, the compound as represented in formula I, *i.e.*, R₁ - A' - Y' - Leu - X' - Z' - B' - R₂ is directed to SEQ ID NO. 8 (*i.e.*, the HHQKLVFF peptide). Moreover, claims 13, 14, 18, and 35-41, as hereby amended, are readable on the elected species. Applicants elect the species with the understanding that the election is for search purposes only and that, should the Examiner find the species to be patentable over the prior art, the Examiner will extend the search to the remaining subject matter defined in the claims.

Applicants note that a species election was previously made with traverse to SEQ ID NO. 8 (*i.e.*, HHQKLVFF) in the Amendment and Reply to Restriction filed on December 2, 2002, and this elected species was to read on amended claims 13, 14, 18, and 35-41. See December 2, 2002 Amendment and Reply to Restriction, page 12. Despite this election, the Office issued an Official Communication on February 21, 2003 indicating that although this election was a *bona fide* attempt, it failed to fully respond to the election of species requirement. See February 21, 2003 Official Communication, page 2.

However, other than a cursory statement that the elected sequence was allegedly not addressed in the claims, the Official Communication did not specifically indicate how the elected peptide SEQ ID NO. 8 (*i.e.*, HHQKLVFF) failed to properly respond to the July 30, 2002 Restriction Requirement. Accordingly, Applicants held a brief telephonic discussion with the Examiner on March 5, 2003 to clarify this matter. During this discussion, the Examiner indicated that the election of SEQ ID NO. 8 does not specifically address each substituent of the compound as represented in formula I, *i.e.*, R₁ - A' - Y' - Leu - X' - Z' - B' - R₂. The Examiner then requested a specific election for each of the substituent: R₁, A', Y', X, Z', B', and R₂. This additional election of each substituent was

not set forth in either the July 30, 2002 Restriction Requirement or the February 21, 2003 Official Communication from the Patent Office. In addition, neither of these Actions gave an explanation as to why each substituent was distinct or why it would require an unduly burdensome search.

Applicants respectfully traverse this characterization that SEQ. ID. NO. 8, the HHQKLVFF peptide is not addressed by the claims. As can be discussed above, the elected HHQKLVFF peptide does in fact read on the claimed compound as represented in formula I, *i.e.*, $R_1 - A' - Y' - \text{Leu} - X' - Z' - B' - R_2$. Moreover, Applicants were following the suggestion of the Examiner by including an election to a specific peptide sequence, *i.e.*, SEQ ID NO. 8. In this regard, Applicants direct the Examiner's attention to page 8, lines 14-16 of the July 30, 2002 Restriction Requirement wherein it states that "Applicants should include a chemical structure (or sequence) of the elected compound if not already contained in the specification." Pursuant to this initiative, Applicants previously elected with traverse the SEQ ID NO. 8 (*i.e.*, the HHQKLVFF peptide) which corresponds to the compound as represented in formula I, *i.e.*, $R_1 - A' - Y' - \text{Leu} - X' - Z' - B' - R_2$ is directed to SEQ ID NO. 8 (*i.e.*, the HHQKLVFF peptide). Thus, the previous Amendment and Reply to Restriction was proper and complete.

Finally, Applicants further traverse the Species Requirement because the July 30, 2002 Restriction Requirement fails to set forth how the alleged plurality of patentably distinct species of peptides require a burdensome search. No indication is given as to how or why the alleged plurality of peptides would require a burdensome search. Likewise, no arguments are set forth specifically indicating how the alleged species are distinct from one another. Only a mere assertion is made that the claims are generic to a plurality of

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patentably distinct species that require a burdensome search. Such is not the proper basis for an election of species requirement.

Thus, for at least all of reasons set forth above, Applicants respectfully traverse the Restriction and Species Requirements, and request their withdrawal.

CONCLUSION


From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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